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## NOTICE OF ALLOWANCE AND FEE(S) DUE

82764 7590 07/15/2010

GRANT ANDERSON LLP  
GRANT ANDERSON LLP C/O PORTFOLIOIP  
P.O. BOX 52050  
MINNEAPOLIS, MN 55402

EXAMINER	
PROCTOR, JASON SCOTT	
ART UNIT	PAPER NUMBER
2123	

DATE MAILED: 07/15/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,725	10/04/2000	Robert g. Whirley	TRI-0255-UT	7345

TITLE OF INVENTION: VIRTUAL PROTOTYPING AND TESTING FOR MEDICAL DEVICE DEVELOPMENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$0	\$0	\$755	10/15/2010

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

**HOW TO REPLY TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

## PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to:** **Mail Stop ISSUE FEE**  
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**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
**or Fax (571)-273-2885**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

82764      7590      07/15/2010

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**P.O. BOX 52050**  
**MINNEAPOLIS, MN 55402**

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

### **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,725	10/04/2000	Robert g. Whirley	TRI-0255-UT	7345

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nonprovisional	YES	\$755	\$0	\$0	\$755	10/15/2010
EXAMINER		ART UNIT	CLASS-SUBCLASS			
PROCTOR, JASON SCOTT		2123	703-012000			

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 \_\_\_\_\_  
2 \_\_\_\_\_  
3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are submitted:

- Issue Fee  
 Publication Fee (No small entity discount permitted)  
 Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- A check is enclosed.  
 Payment by credit card. Form PTO-2038 is attached.  
 The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

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Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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82764	7590	07/15/2010	EXAMINER	
GRANT ANDERSON LLP				PROCTOR, JASON SCOTT
GRANT ANDERSON LLP C/O PORTFOLIOIP				ART UNIT
P.O. BOX 52050				PAPER NUMBER
MINNEAPOLIS, MN 55402				2123
				DATE MAILED: 07/15/2010

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 570 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 570 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/679,725	WHIRLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JASON PROCTOR	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 4/27/2010.
2.  The allowed claim(s) is/are 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-125.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 2/26/2001 - corrected
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

/Jason Proctor/  
Primary Examiner, Art Unit 2123

**DETAILED ACTION**

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-125 were rejected in the Office Action entered on 27 October 2009.

Applicants' response submitted on 27 April 2010 has amended claims 1, 11, 16, 26, 31, 38, 54, 62, 64, 70, 78, 80, 86, 91, and 93. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-125 are pending in this application.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-125 are allowed.

***Information Disclosure Statement***

1. The Information Disclosure Statement submitted on 26 February 2001 cited a reference to "Hoover et al." and "Tanaka et al." without providing at least a year of publication. Further, the Examiner is unable to identify a publication date within the references themselves. Therefore, these citations have been lined through because they do not meet the requirements of 37 CFR 1.98.

Please find attached a corrected initialed copy of the IDS submitted on 26 February 2001.

***Claim Interpretation - 35 USC § 101***

2. Independent claims 54, 70, and 86 recite methods that do not transform an underlying article to a different state or thing and are not explicitly tied to any particular apparatus or machine. However, these claims each recite method steps that, in light of the specification, could not be reasonably interpreted as being performed except by a computer apparatus.

Specifically, would be understood by a person of ordinary skill in the art at the time the invention was made, in light of the disclosure, the step of "simulating an interaction between said anatomical feature(s) and said candidate medical device design over at least one dynamic expansion and contraction cycle of the anatomical feature(s) with a stress/strain/deformation analyzer to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data," would inherently be tied to a computer apparatus for performing this simulation. Therefore, for at least this reason, the Examiner determines that the method of claims 54, 70, and 86 are statutory methods for the purposes of 35 U.S.C. § 101.

### ***Reasons for Allowance***

3. The following is an examiner's statement of reasons for allowance:

In response to the 35 U.S.C. § 103(a) rejections in the previous Office Action, Applicants argue primarily that:

Neither Witcher nor Chong teach or suggest a mesh generator that generates a single finite element model representing both an anatomical feature and medical device together. Witcher teaches a rudimentary finite element model of a stent, but not a finite element model of an anatomical feature. Chong teaches a surface triangulation of an arterial wall for use in machining or surface milling acrylic plastic blocks to create a physical model of an aneurysm for bench test or laboratory test purposes. However, Chong does not teach a finite element model. In addition, the data produced by the methods of Chong would not be suitable for analysis by finite element analyzer. Therefore, even if combined, the references fail to teach or suggest the claimed limitations.

The Examiner has fully considered this argument and finds it persuasive. The previous rejection relied upon Chong to teach a mesh model of an anatomical feature as related to the claim language, however the present amendments require a finite element model of an anatomical

feature, in combination with the other claimed elements. The prior art of record fails to teach or suggest such a feature.

Further, an updated search of the prior art fails to reveal references that teach or suggest the claimed features. In addition to the references previously made of record, the Examiner considers the following reference to De Hart to be relevant.

The reference "A three-dimensional analysis of a fibre-reinforced aortic valve prosthesis" by J. De Hart, et al., teaches a finite element model of a prosthetic device (abstract) and simulates the stresses, strain, and deformation in the device during operation (see, for example, Figs. 9 and 10), but does not teach or suggest generating a combined finite element model of both an anatomical feature *and* a medical device, and does not teach simulating the *interaction* of the medical device with the anatomical feature over at least one dynamic expansion and contraction cycle of the anatomical feature.

Therefore, the allowable subject matter is found in the claims, in particular:

(Claims 1, 16, and substantially similar language in Claim 31) *a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device; and*

*a stress/strain/deformation analyzer that receives said finite element model, [...] and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the anatomical feature(s) to determine the*

*predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature(s)*

*(Claims 54, 70, and substantially similar language in Claim 86) generating a finite element model representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design with a mesh generator; [...] and simulating an interaction between said anatomical feature(s) and said candidate medical device design over at least one dynamic expansion and contraction cycle of the anatomical feature(s) with a stress/strain/deformation analyzer to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data in combination with the other claimed elements.*

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason Proctor/  
Primary Examiner, Art Unit 2123

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